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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/870,899

Filing Date: May 31, 2001 Appellant(s): WILSON ET AL.

Rebecca L. Ball For Appellant

**EXAMINER'S ANSWER** 

This is in response to the appeal brief filed August 30, 2004.

## (1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

## (2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

## (3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

#### (4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

## (5) Summary of Invention

The summary of invention contained in the brief is correct.

#### (6) Issues

The appellant's statement of the issues in the brief is correct.

# (7) Grouping of Claims

The rejection of claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-102 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

## (8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

### (9) Prior Art of Record

Fritsche et al., "Enrichment of Omega-3 Fatty Acid in Sucking Pigs by Maternal Dietary Fish Oil Supplement", J. Anim. Sci. Vol. 71, (1993), page 1841-1847.

Boudreaus et al. "The Effects of Varying Dietary n-6 to n-3 Fatty Acid Ratios on Platelet Reactivity, Coagulation Screening Assays, an Antithrombin III Activity in Dogs", J. Am. Animal Hospital Association, Vol.33, (1997), page 235-243.

Abayasekare et al. "Effects of Altering Dietary Fatty Acid Composition on prostaglandin Synthesis and Fertility", Prostaglandins, Leukotrienes and Essential Fatty Acids, Vol.61(5), (1999), page 275-287.

## (10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-102, are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritsche et al. (of record) in view of

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Boudreaus et al. (of record). This rejection is set forth in the prior Office Action mailed November 19, 2003, and reiterated as below.

Fritsche et al. discloses that fish oil compositions (menhaden fish oil) which is known to comprise C20 and C22 omega-3 fatty acids including eicosapentaenoic acid and also comprise omega-6 fatty acids (see abstract, especially Table 1 at the left column of page 1842, and Table 2 at the right column of page 1843) are useful in dietary compositions to feed sows (female swine) including gestation until farrowing and lactation and methods of the treatment to benefit sow's performance in maternal period including gestation until farrowing and lactation, and benefit pig survival, number of pigs born per sow, birth weight and weaning weights (see title of the article, abstract, Introduction, and working examples in "Animals and Diets" at the right column of page 1841 to the left column of page 1842). Fritsche et al. also discloses the effective amounts of fish oil in the feed compositions to be administered daily, e.g., 3.5 or 7.0%, and vitamin mix (known antioxidants) in the feed compositions (see abstract, especially Table 1 at the left column of page 1842).

Fritsche et al. does not expressly disclose the particular amounts (percentage) of fish oil in the composition there, 0.025% to 2% by weight, or the particular amounts fish oil such as salmon oil in the composition therein, and the ratio of omega-6 to omega-3 fatty acids, and the particular time for the administration such as about 30 days before a first mating through a second mating, and stabilizing the fish oil by prilling.

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Boudreaux et al. discloses that the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is within the instant claim. See abstract and page 236 3<sup>rd</sup> paragraph of left column.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions and to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions since the effective amounts <u>up to 3.5 or 7%</u> of fish oil in the feed composition of Fritsche et al. are known in the art.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein, since the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is known according to Boudreaux et al.

Moreover, the optimization of known effective amounts of known active agents to be administered based on the disclosures of the prior art is considered well in the competence level of an ordinary skilled artisan, involving merely routine skill in the art, especially considered well within **conventional** skills in animal science and animal feed industry.

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It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Additionally, Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see Applicant's admission regarding the prior art at page 2 lines 29-30 of the specification). Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25 of the specification). It is noted that Applicant clearly cited the prior art references, i.e., journal articles and patents, for these prior art teachings in the specification.

Further, Salmon oil or menhaden oil is well known to contain C20 and C22 omega-3 fatty acids and omega-6 fatty acids. C20 and C22 omega-3 fatty acids and omega-6 fatty acids are known to benefit female swine performance. Therefore, one of ordinary skill in the art would have found it obvious to employ Salmon oil or menhaden oil as fish oil and determine the particular amounts (percentage) of fish oil and the time for the administration such as about 30 days before a first mating through a second mating based the prior art teachings.

Furthermore, one of ordinary skill in the art would have found it obvious to stabilize the fish oil in the feed by prilling since prilling is known as an art recognized technique for stabilizing fish oil.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

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Claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-102, are rejected under 35
U.S.C. 103(a) as being unpatentable Abayasekare et al. (of record). This rejection is set forth in the prior Office Action mailed November 19, 2003, and reiterated as below.

Abayasekare et al. discloses that dietary fatty acid compositions, i.e., fish oil, comprising instant fatty acids such as omega-6 fatty acids to omega-3, and the their ratio of (see particularly Fig 1 at page 277) are useful in increasing the female performance, i.e., follicular development in the ovary, ovaulation, corpus luteum function, pregnancy, parturition, and lactation (see abstract, page 279-282).

Abayasekare et al. does not expressly disclose the dietary fatty acid compositions therein to be administered to female swine, and the particular amounts (percentage) of fish oil in the composition there, 0.025% to 2% by weight, or the particular amounts fish oil such as salmon oil in the composition therein, and the ratio of omega-6 to omega-3 fatty acids, and the particular time for the administration such as about 30 days before a first mating through a second mating, and stabilizing the fish oil by prilling.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer the dietary fatty acids to the particular female, swine in methods of increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the reproductive performance of a breeding population of a female swine. It would also have been obvious to a person of ordinary skill in the art at the time the invention was

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made to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions and to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to administer the dietary fatty acids to the particular female, swine in methods of increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the reproductive performance of a breeding population of a female swine, since it is known that dietary fatty acid compositions, i.e., fish oil, comprising instant fatty acids are useful in increasing the female performance, i.e., follicular development in the ovary. ovaulation, corpus luteum function, pregnancy, parturition, and lactation, according to Abayasekare et al. One of ordinary skill in the art would acknowledge that female performance taught by Abayasekare et al. would encompass female swine. Therefore, one of ordinary skill in the art would have found it obvious to employ these fatty acids dietary composition to feed female swine for increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine. or increasing the reproductive performance of a breeding population of a female swine, with the reasonable expectation of success.

Additionally, Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see Applicant's admission regarding the prior art at page 2 lines

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29-30 of the specification). Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25 of the specification).

Moreover, as discussed above (see supra page 5-6) the optimization of known effective amounts of known active agents to be administered based on the disclosures of the prior art is considered well in the competence level of an ordinary skilled artisan, involving merely routine skill in the art, especially considered well within **conventional** skills in animal science and animal feed industry.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

#### (11) Response to Argument

## Claim Rejections - 35 USC § 103 Maintained

Claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-72 as amended now, and new claims 73-102, are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritsche et al. (of record) in view of Boudreaus et al. (of record).

It is the examiner's position that the present invention is clearly obvious in view of the prior art of record, as discussed below.

Fritsche et al. discloses that fish oil compositions (menhaden fish oil) which is known to comprise C20 and C22 omega-3 fatty acids including eicosapentaenoic acid

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and also comprise omega-6 fatty acids (see abstract, especially Table 1 at the left column of page 1842, and Table 2 at the right column of page 1843) are useful in dietary compositions to feed sows (female swine) including gestation until farrowing and lactation and methods of the treatment to benefit sow's performance in maternal period including gestation until farrowing and lactation, and benefit pig survival, number of pigs born per sow, birth weight and weaning weights (see title of the article, abstract, Introduction, and working examples in "Animals and Diets" at the right column of page 1841 to the left column of page 1842). Fritsche et al. also discloses the effective amounts of fish oil in the feed compositions to be administered daily, e.g., 3.5 or 7.0% by weight, and vitamin mix (known antioxidants) in the feed compositions (see abstract, especially Table 1 at the left column of page 1842).

Fritsche et al. does not expressly disclose the particular amounts (percentage) of fish oil in the composition there, i.e., about 0.025%-2% by weight, and the ratio of omega-6 to omega-3 fatty acids, and the particular time for the administration such as about 30 days before a first mating through a second mating, and stabilizing the fish oil by prilling.

Boudreaux et al. discloses that the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is within the instant claim by showing the effects of varying dietary n-6 to n-3 fatty acid ratios in animal diets. See abstract and page 236 3<sup>rd</sup> paragraph of left column.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the amount of fish oils to 0.025% to 2% by weight in the

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prior art compositions and to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions since the effective amounts <u>up to 3.5 or 7%</u> of fish oil in the feed composition of Fritsche et al. are known in the art. Note that <u>3.5% by weight taught by the prior art may be reasonably interpreted as about 2% by weight or substantially close to about 2%, as claimed herein.</u>

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein, since the range of the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals is known according to Boudreaux et al.

Moreover, the optimization of known effective amounts of known active agents to be administered based on the disclosures of the prior art is considered well in the competence level of an ordinary skilled artisan, involving merely routine skill in the art, especially considered well within **conventional** skills in animal science and animal feed industry.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

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Additionally, Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see Applicant's admission regarding the prior art at page 2 lines 29-30 of the specification). Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25 of the specification). It is noted that Applicant clearly cited the prior art references, i.e., journal articles and patents, for these prior art teachings in the specification.

Further, Salmon oil or menhaden oil is well known to contain C20 and C22 omega-3 fatty acids and omega-6 fatty acids. C20 and C22 omega-3 fatty acids and omega-6 fatty acids are known to benefit female swine performance. Therefore, one of ordinary skill in the art would have found it obvious to employ Salmon oil or menhaden oil as fish oil and determine the particular amounts (percentage) of fish oil and the time for the administration such as about 30 days before a first mating through a second mating based the prior art teachings.

Furthermore, one of ordinary skill in the art would have found it obvious to stabilize the fish oil in the feed by prilling since prilling is known as an art recognized technique for stabilizing fish oil.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

First, Appellants argue that Fritsche et al. teach away from the invention of claim 1 herein by citing page 1843, column 1, paragraph 2. Appellants' argument is not found convincing, since the reference of Fritsche et al. as a whole, teaches and fairly suggests that fish oil compositions (e.g., menhaden fish oil) which is known to comprise C20 and

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C22 omega-3 fatty acids including eicosapentaenoic acid and also comprise omega-6 fatty acids are useful in dietary compositions to feed sows (female swine) including gestation until farrowing and lactation and methods of the treatment to benefit sow's performance in maternal period including gestation until farrowing and lactation, and benefit pig survival, number of pigs born per sow, birth weight and weaning weights (see title of the article, abstract, Introduction in particular, and working examples in "Animals and Diets" at the right column of page 1841 to the left column of page 1842 and Table 2 at the right column of page 1843). As noted in MPEP 2123:

"A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v.Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied,493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

Therefore, the reference of Fritsche et al. as a whole is seen to render the claimed invention obvious, <u>not</u> teaching away as Appellants assert.

Secondly, Appellants argue that Boudreaux et al. does not overcome the insufficiencies of Fritsche et al. because Boudreaux et al. does not provide the teaching of "a method of increasing the reproductive performance of a female swine" that is lacking in Fritsche et al. Appellants' argument is not found persuasive.

Boudreaux et al. has been cited by the examiner as a secondary reference for its teachings that optimizing or determining the ratio of omega-6 fatty acids to omega-3 fatty acids herein in the composition to be administered to animals based on the known teachings of Boudreaux et al. that discloses the range is within the instant claim by showing the effects of varying dietary n-6 to n-3 fatty acid ratios in animal diets, is considered well within **conventional** skills in animal science and animal feed industry.

Additionally, note that Appellants clearly cite the prior art references, i.e., journal articles and patents, for these prior art teachings in the specification, i.e., Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see Applicant's admission regarding the prior art at page 2 lines 29-30 of the specification). Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25 of the specification). Further, Salmon oil or menhaden oil is well known to contain C20 and C22 omega-3 fatty acids and omega-6 fatty acids. C20 and C22 omega-3 fatty acids are known to benefit female swine performance. See "Background of Invention" at page 1-3 of specification, even though Appellants ague that all teachings described in "Background of Invention", in particular page 2 line 17 to page 3 line 4, are not Appellants' admission as prior art. As noted in MPEP 2129 "Admissions as Prior Art":

\*\*>A statement by an applicant during prosecution <u>identifying</u> the work of <u>another as prior art</u>" is an admission that that work is available as prior art against the claims, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. Riverwood Int 'I Corp. v. R.A. Jones & Co.,324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed Cir. 2003). However, even if

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labeled as "prior art," the work of the same inventive entity may not be considered prior art against the claims unless it falls under one of the statutory categories. Id.; see also Reading & Bates Construction Co. v. Baker Energy Resources Corp., 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984) ("[W]here the inventor continues to improve upon his own work product, his foundational work product should not, without a statutory basis, be treated as prior art solely because he admits knowledge of his own work. It is common sense that an inventor, regardless of an admission, has knowledge of his own work."). Consequently, the examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. In the absence of another credible explanation, examiners should treat such subject matter as the work of another." (emphasis added).

It must be recognized that any judgment on obviousness takes into account knowledge which was available and within the level of ordinary skill at the time the claimed invention was made.

Therefore, in response to Appellants' argument that there is no motivation to combine the prior art, the motivation to combine the teachings of the prior art cited herein and knowledge which was available and within the level of ordinary skill at the time the claimed invention was made (i.e., "Background of Invention" of the specification), to make the present invention is clearly seen. The claimed invention is clearly obvious in view of the prior art.

Most importantly, Appellants' data shown in the Examples 1-5 of the specification at pages 15-26 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. The results herein, i.e., the reproductive performance

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of a female swine, e.g., the total numbers of born pigs and born alive were observed slightly increasing, compared to the control (see in particular page 17-18), are clearly expected and not unexpected based on the cited prior art, Fritsche et al., as discussed above. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Therefore, the evidence presented in Examples herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

Moreover, Examples 1-5 provide no clear and convincing evidence of nonobviousness or unexpected results since there is no comparison to the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Claims 1-6, 8-9, 13-20, 23, 25, 41 and 71-102, are rejected under 35 U.S.C. 103(a) as being unpatentable Abayasekare et al. (of record).

It is the examiner's position that the present invention is clearly obvious in view of the prior art of record, as discussed below.

Abayasekare et al. discloses that dietary fatty acid compositions, i.e., fish oil, comprising instant fatty acids such as omega-6 fatty acids to omega-3, and the their ratio, e.g., greater than 10 (see Abstract and Fig 1 at page 277) are useful in increasing the female performance, i.e., follicular development in the ovary, ovaulation, corpus luteum function, pregnancy, parturition, and lactation (see abstract, page 279-282).

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Abayasekare et al. does not expressly disclose the dietary fatty acid compositions therein to be administered to female swine, and the particular amounts (percentage) of fish oil in the composition there, 0.025% to 2% by weight, or the particular amounts fish oil such as salmon oil in the composition therein, and the ratio of omega-6 to omega-3 fatty acids, and the particular time for the administration such as about 30 days before a first mating through a second mating, and stabilizing the fish oil by prilling.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer the dietary fatty acids to the particular female, swine in methods of increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the reproductive performance of a breeding population of a female swine. It would also have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the amount of fish oils to 0.025% to 2% by weight in the prior art compositions and to optimize the particular ratio of omega-6 fatty acids to omega-3 fatty acids herein in the compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to administer the dietary fatty acids to the particular female, swine in methods of increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the

reproductive performance of a breeding population of a female swine, since it is known that dietary fatty acid compositions, i.e., fish oil, comprising instant fatty acids are useful in increasing the female performance, i.e., follicular development in the ovary, ovaulation, corpus luteum function, pregnancy, parturition, and lactation, according to Abayasekare et al. One of ordinary skill in the art would acknowledge that female performance taught by Abayasekare et al. would encompass female swine. Therefore, one of ordinary skill in the art would have found it obvious to employ these fatty acids dietary composition to feed female swine for increasing the reproductive performance of a female swine, increasing the number of live births to a female swine, increasing the total number of births to a female swine, increasing the farrowing rate of a female swine, or increasing the reproductive performance of a breeding population of a female swine, with the reasonable expectation of success.

Additionally, Omega-3 fatty acids in particular are known to be useful to increase female animal fertility (see Applicant's admission regarding the prior art at page 2 lines 29-30 of the specification). Omega-6 fatty acids are known to increase the number of live births in animals (see page 2 lines 24-25 of the specification).

Moreover, as discussed above (see supra page 5-6) the optimization of known effective amounts of known active agents to be administered based on the disclosures of the prior art is considered well within the competence level of an ordinary skilled artisan, involving merely routine skill in the art, especially considered well within **conventional** skills in animal science and animal feed industry.

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It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

First, Appellants assert that the cite prior art teaches the effects of the instant fatty acids on the reproductive performance of ruminants; swine are not rumination. However, Abayasekare et al. teaches that species such as human, cow, pig, rat, are known to have dietary intake of the fatty acids herein (see page 279, the left column) and "Effects of altering dietary fatty acids on Female reproduction" broadly and in general (see page 279-281).

Most importantly, Appellants provide no clear and convincing <u>evidence</u> of <u>unexpected results</u> for treating female pigs or swine over the prior art to rebut the prima facie case herein. In this regard, it is noted that the specification provides no <u>side-by-side</u> comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art, as discussed above.

Again, Appellants' assertion in the declaration of Dr. Donal E. Orr (inventor) submitted February 10, 2003 under 37 CFR 1.132, with respect to that Applicants' claimed invention has met with great commercial success, have been fully considered but are not deemed persuasive. As discussed in the interview on October 15, 2003 regarding the instant case and the parent Application, the examiner directs Appellants' attention to MPEP 716.03(a) stating:

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"Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. In re Tiffin, 448 F.2d 791, 171 USPQ 294 (CCPA 1971) (evidence showing commercial success of thermoplastic foam "cups" used in vending machines was not commensurate in scope with claims directed to thermoplastic foam "containers" broadly). In order to be commensurate is scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features. Joy Technologies Inc. v. Manbeck, 751 F. Supp. 225, 229, 17 USPQ2d 1257, 1260 (D.D.C. 1990), aff 'd, 959 F.2d 226, 228, 22 USPQ2d 1153, 1156 (Fed. Cir. 1992) (Features responsible for commercial success were recited only in allowed dependent claims, and therefore the evidence of commercial success was not commensurate in scope with the broad claims at issue.).

An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the] patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. Ex parte Standish, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988)."

Secondly, Applicant's attention is directed to MPEP 716.03(b) stating:

"Gross sales figures do not show commercial success absent evidence as to market share, Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, Ex parte Standish, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988)."

In the instant case, as discussed in the Final Rejection, the declaration merely shows the value of sales (US dollars) per the number pounds sold in the monthly sales

for 2002 for Appellants' product Fertilium<sup>TM</sup>, and the projected prediction of sale by 2004, absent a <u>full</u> market information and comparison, for example, with all other competitors and prices, and real sale information. Thus, the declaration of Dr. Donal E. Orr is insufficient to establish the fact that Applicants' claimed invention has met with great commercial success.

Therefore, as discussed above, the declarations of Dr. Stephen K. Webel, Dr. Douglas M. Webel (inventor), and Dr. Donald E. Orr (inventor) are ineffective to overcome the set forth 103(a) rejections.

The declaration of Dr. Douglas M. Webel (inventor) submitted October 28, 2003 under 37 CFR 1.132, with respect to the composition of Fertilium<sup>TM</sup>, has been fully considered. However, the exact and precise scope of the composition of Fertilium<sup>TM</sup>, is not clearly disclosed, i.e., no <u>factual</u> documentary evidence is provided in support of the composition of Fertilium<sup>TM</sup>. Hence, it is still unclear whether the evidence of commercial success asserted by Appellants is commensurate in scope with the claims, because the instant specification and the declaration fail to disclose what ingredients or agents in Appellants' product Fertilium<sup>TM</sup>.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

S. A. Jiang, Ph.D. Primary Examiner November 26, 2004 BAADIA ANNA JIANG PATENT EXAMINER

Conferees

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